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Food Branch, Canada) for the Office's consideration. Exhibits B and C are being submitted as evidence that the hydrocortisone-containing formulations, such as those disclosed in Chen, are solely for external use only and are not suitable for use in a vagina.

1. Rejection of Claims 1-4, 6-11, and 14-25 for
Obviousness Type Double Patenting

Claims 1-4, 6-11, and 14-25 have been rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of Syverson (U.S. Patent No. 6,281,999)¹ in view of D'Augustine et al. (U.S. Patent No. 6,416,779).

Under M.P.E.P. §804, a rejection of double patenting requires that "two or more patents or applications have at least one common inventor and/or be either commonly assigned/owned or non-commonly assigned/owned but subject to a joint research agreement as set forth in 35 U.S.C. §§103(c)(2) and (3) pursuant to the CREATE Act." U.S. Patent No. 6,281,999 does not have a common inventor and is not commonly assigned/owned with the instant application. Specifically, U.S. Patent No. 6,281,999 was issued to Michael Watson and Allan Hamilton and assigned to Zilog, Inc., while the inventors of the instant application are Rae Ellen Syverson and Richard A. Proctor and the instant application is assigned to Kimberly-Clark Worldwide, Inc. As

¹ Applicants note that Syverson is not an inventor on U.S. Patent No. 6,281,999. U.S. Patent No. 6,281,999 was issued August 28, 2001 to Michael Watson and Allan Hamilton, both of San Jose, California.

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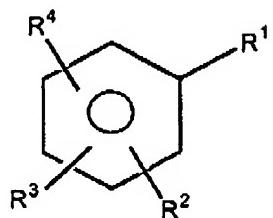
evidence, Applicants enclose herewith the Notice of Recordation of Assignment Document and the Assignment Document for the instant application (Exhibit A). As such, this double patenting rejection is improper and should be withdrawn.

2. Rejection of Claims 1-4 and 6-10 Under 35 U.S.C.

§103(a)

Reconsideration is requested of the rejection of claims 1-4 and 6-10 under 35 U.S.C. §103(a) as being unpatentable over Stolar (U.S. 4,470,978) in view of D' Augustine et al. (U.S. 6,416,779) or over Chen (U.S. 5,728,690) and D'Augustine et al. in view of Stolar.

Claim 1 is directed to an exoprotein inhibitor for inhibiting the production of exoproteins from Gram positive bacteria in and around a vagina. The exoprotein inhibitor comprises a non-absorbent substrate for insertion into the vagina being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche. The non-absorbent substrate has deposited thereon an effective amount of a first active ingredient having the general formula:



wherein R¹ is -OR⁶OH; R⁶ is a divalent saturated or unsaturated

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aliphatic hydrocarbyl moiety; R², R³, and R⁴ are independently selected from the group consisting of H, OH, COOH, and -C(O)R⁹; R⁹ is hydrogen or a monovalent saturated or unsaturated aliphatic hydrocarbyl moiety, wherein the first active ingredient is effective in inhibiting the production of exoprotein from Gram positive bacteria.

Stolar discloses an antibacterial pharmaceutical composition to treat bacterial infections comprising effective amounts of a combination of phenoxyethanol, trimethoprim, and an antibacterial sulfa drug. The composition is for internal administration, and can be distributed in a pharmaceutically acceptable carrier. Examples of suitable carriers include sugar, dextrin, dextrose, sodium chloride, and the like.²

As noted by the Office in the Office action dated November 30, 2005, Stolar fails to disclose a non-absorbent substrate for insertion into the vagina being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche. In an attempt to find each and every element of claim 1 as required by the M.P.E.P. for a determination of *prima facie* obviousness, the Office cites either the D'Augustine et al. reference alone or in combination with the Chen reference for combination with Stolar.

D' Augustine et al. disclose devices, methods, and compositions for treating vaginal fungal, bacterial, viral, and parasitic infections by intravaginal or transvaginal

² Applicants note that, as discussed in more detail below, Stolar does not disclose phenoxyethanol as an antibacterial agent; he only describes phenoxyethanol as a single component of a three-component antibacterial composition. Stolar fails to disclose that phenoxyethanol alone has antibacterial properties.

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administration of therapeutic and/or palliative antifungal, antibacterial, antiviral or parasiticidal drugs to the vagina or to the uterus. Specifically, a device such as a tampon, tampon-like device, vaginal ring, pessary, cervical cup, vaginal sponge, intravaginal tablet, or intravaginal suppository, delivers the drug, which can be in the form of a paste, cream, ointment, microcapsule, solution, powder, or gel having a sufficient thickness to maintain prolonged vaginal epithelium and mucosa contact. In one embodiment, the drug can be incorporated into a cream, lotion, foam, paste, ointment, or gel which can be applied to the vagina using an applicator.³

Chen is directed to a clear, non-alcoholic hydrocortisone solution for external application to the skin directly, or by a wipe, as a treatment for temporary relief of itching associated with minor skin irritation, inflammation and rashes. Specifically, the solution is free of lower alcohols such as ethanol, propanol, or isopropanol, and dissolution of the hydrocortisone is accomplished using the anionic surfactant sodium dioctyl sulfosuccinate. The solution is practically invisible when applied to the skin, and does not irritate or dry the skin or give the stinging sensation of an alcohol containing solution. The hydrocortisone solution set forth in Example 2 comprises hydrocortisone, along with water, and 2-phenoxyethanol. As noted in column 1, lines 8-10, the clear alcohol-free hydrocortisone compositions are useful for the external treatment of skin irritations, itching, and rashes.

In order for the Office to show a *prima facie* case of

³ D' Augustine et al. at column 18, lines 24-26.

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obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art references must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references, and (3) there must be some reasonable expectation of success. The Office has failed to meet its burden under (2) above, as there is no motivation or suggestion to combine the Stolar and D' Augustine et al. and/or Chen references to arrive at Applicants' claim 1.

As noted in M.P.E.P. §2142, in establishing obviousness, the Office must show references that teach all of the claimed limitations along with some motivation or suggestion, either in the references themselves or in knowledge generally available to one skilled in the art, to combine the references and arrive at the claimed subject matter.⁴ The mere fact that the references can be combined to arrive at the claimed subject matter does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. *In re Mill*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). A close reading of the cited references clearly indicates that one skilled in the art would not have been so motivated and, without Applicants' disclosure as a blueprint (which the Office had the

⁴As further set forth in M.P.E.P. §2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the reference itself, or in the knowledge generally available to one of ordinary skill in the art.

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benefit of utilizing), such a combination of the Stolar, D' Augustine et al., and Chen references would not have been made.⁵

The Office first asserts that, as Stolar teaches phenoxyethanol as an effective antibacterial agent and D'Augustine discloses effective delivery of antibacterial compounds through non-absorbent vaginal devices, it would have been obvious for one skilled in the art at the time of the instant invention to add the phenoxyethanol of Stolar to the non-absorbent devices of D'Augustine for treating microbial or bacterial infections in the vaginal area. Alternatively, the Office asserts that it would have been obvious for one of ordinary skill in the art to use the hydrocortisone of Chen comprising phenoxyethanol on non-absorbent devices such as the douche of Chen or the non-absorbent devices taught in D'Augustine. With all due respect, Applicants submit that neither of these assertions provides the required convincing lines of reasoning as to why the combination of these references would have been obvious to one skilled in the art at the time of

⁵M.P.E.P. §2142 further provides that in order to reach a proper determination under 35 U.S.C. §103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. Knowledge of Applicants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences." The tendency to resort to "hindsight" based upon Applicants' disclosure is often difficult to avoid due to the very nature of the examination process. However, as stated by the Federal Circuit, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. Grain Processing Corp. v. American-Maize-Products, Co., 840 F.2d 902, 904 (Fed. Cir. 1988).

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the invention. Specifically, even assuming that the Stolar and/or Chen composition is disclosed as suggested by the Office, why would one skilled in the art pick Stolar's or Chen's composition over all of the other non-toxic, antibacterial compositions present in the art, particularly when the D'Augustine et al. provide numerous suitable antibacterial compositions to use with their non-absorbent devices and do not point to any need for alternatives?

D' Augustine et al. simply teach compositions that can be used as antibacterials to treat bacterial infections of the vagina and devices for delivering the compositions; and even provide several commercially acceptable antibacterial compositions. The D' Augustine et al. reference fails to provide a reason why one skilled in the art would choose another antibacterial over those listed in the D' Augustine et al. reference or disclosed elsewhere in the art. The Stolar reference is directed to antibacterial compositions suitable for administration, particularly oral administration, to treat bacterial infections in humans and animals. For example, in Example 6, chicks were orally treated for *E. coli* infection of the peritoneum area by mixing the Stolar antibacterial composition with the chicks' drinking water. As such, why would one skilled in the art look to the Stolar antibacterial, orally-administered composition over any other antibacterial compositions for use in the intravaginal devices of D' Augustine et al.? No where in Stolar is it disclosed to use the antibacterial composition for the treatment of vaginal fungal, bacterial, viral, and parasitic infections. Additionally, one skilled in the art could not have been motivated to use solely

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phenoxyethanol from the three-drug cocktail disclosed by Stolar. Why would one skilled in the art pick phenoxyethanol without the other two components? As such, one skilled in the art would not, and could not, be motivated to use the antibacterial composition of Stolar over any other antibacterial composition in the intravaginal devices of D' Augustine et al. to arrive at each and every limitation of Applicants' claim 1.

Furthermore, the Chen reference also fails to provide motivation or suggestion to combine the cited references as required by M.P.E.P. §2142 for a *prima facie* case of obviousness, and would actually dissuade one skilled in the art from using her composition in a vagina. Significantly, as noted above, Chen's compositions are solely for external treatment of skin only, and not for internal vaginal cleansing. There is no disclosure that any of the alcohol-free hydrocortisone formulations of Chen could be useable internally, let alone on intravaginal devices such as disclosed by D'Augustine et al.

As noted above, Applicants enclose Exhibits B ("Vaginal Problems" Johns Hopkins University) and C ("Hydrocortisone - Labeling Standard" Health Products and Food Branch, Canada) as further evidence that the hydrocortisone formulation of Chen, and hydrocortisone-containing formulations in general, are not suitable for use in a vagina as hydrocortisone is for external use only and, if contacted with the vaginal wall, can cause thinning of the vaginal tissue.⁶

In the Office action, the Office states that Chen discloses a douche. Specifically, the only passage of Chen that refers to

⁶ Vaginal Problems at page 4.

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a douche reads, in total:

"U.S. Patent No. 4,778,060⁷ describes a 0.5% hydrocortisone aqueous solution for use as a douche and for impregnating toiletries for wipes."

This passage is found in the background section of the Chen reference, and is describing the prior art patent, not Chen's invention of alcohol-free hydrocortisone compositions.

Significantly, there is no mention or teaching that any of the hydrocortisone compositions of Chen could be utilized as a douche formulation, which is used inside of a vagina.

Importantly, Chen notes at column 1, lines 8-10, that the compositions are for "external treatment⁸" of skin. Thus, the Chen reference does not disclose or suggest a douche formulation.

Applicants further note that Endicott, et al. (U.S. 4,788,060), which, as noted above, is cited in the Chen reference, solely discloses the use of hydrocortisone in a wipe solution suitable for external use only. Although Endicott et al. do also disclose a douche composition suitable for internal cleansing of the vagina, the douche formulation does not

⁷ Applicants note that U.S. Patent No. 4,778,060 is incorrectly cited in the Chen specification. It should read "U.S. Patent No. 4,788,060."

⁸ That the Chen solutions are only suitable for use externally is further evidenced at column 2, lines 28-33 where Chen notes: "The invention solutions of hydrocortisone can be applied externally to the skin as a liquid by rubbing the liquid composition on the skin...." There is no disclosure that the

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comprise any hydrocortisone.

As such, one skilled in the art, would not and could not be motivated to use the hydrocortisone composition of Chen, which could be harmful if used internally, in the intravaginal devices of D'Augustine et al.

With all due respect, it appears that the Office has used impermissible hindsight analysis and reconstruction when combining the Stolar, D' Augustine et al., and/or Chen references to arrive at Applicants' claim 1. Notably, it would be clear to one skilled in the art reading D' Augustine et al. that an antibacterial composition could be used to treat bacterial vaginal infections. There are, however, a myriad of antibacterial compositions, many of which are used to treat vaginal infections. What is important is that there is no motivation or suggestion to use the compositions of Stolar or Chen over any of the other enormous number of antibacterial compositions described in the art, which are suitable for use in a vagina.⁹

compositions of Chen are suitable for internal use, especially inside of a vagina.

⁹ It is noted that the Office states that Stolar teach phenoxyethanol as an effective antibacterial agent. As noted herein, Applicants respectfully note that Stolar does not teach phenoxyethanol as an antibacterial agent, but teaches a cocktail of three drugs as such. Regardless, it is worth noting at this time that the first active ingredient used in the exoprotein inhibitor of claim 1 of the present invention is not acting as an antimicrobial agent as apparently understood by the Office. As mentioned in Applicants' specification, the first active ingredient acts to inhibit the production of exoproteins from Gram positive bacteria, but does not seek to kill the bacteria as the killing of bacteria is non-selective and the "good" bacteria needed to maintain a healthy vagina would also be

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As there is no motivation or suggestion to combine the Stolar, D' Augustine et al. and/or Chen references to arrive at each and every limitation of claim 1, claim 1 is patentable over Stolar in view of D'Augustine et al. or Chen and D'Augustine et al. in view of Stolar.

Claims 2-4 and 6-10 depend directly or indirectly on claim 1. As such, claims 2-4 and 6-10 are patentable for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

3. Rejection of Claims 11-13 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 11-13 under 35 U.S.C. §103(a) as being unpatentable over a combination of Stolar (U.S. 4,470,978) and D' Augustine et al. (U.S. 6,416,779) or over Chen (U.S. 5,728,690) and D'Augustine et al. in view of Stolar and further in view of Muntwyler et al. (U.S. 4,339,462).

Claims 11-13 depend from claim 1 and further require the exoprotein inhibitor to comprise a second active ingredient, wherein the second active ingredient comprises a compound with an ether, ester, amide, glycosidic, or amine bond linking a C₈-

killed. Thus, the non-selective killing of bacteria could actually be very harmful to the vagina and could cause serious health problems. This is significant. The first active ingredient as claimed in claim 1 of the present invention actually seeks not to act as an antimicrobial agent as claimed by the Office, but seeks to only prevent the production of potentially harmful by-products of bacteria, while allowing the bacteria to live. It is also noted that none of the cited references suggest or disclose that a composition having the general formula of the first active ingredient of claim 1 can act in such a manner.

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C₁₈ fatty acid to an aliphatic alcohol. Claim 1 is patentable for the reasons set forth above. Therefore, claims 11-13, which depend from claim 1, are patentable for the same reasons as claim 1 above. In particular, there is no motivation to combine the Stolar, D'Augustine, and/or Chen references to arrive at each and every limitation of claim 1.

Muntwyler et al. fail to overcome the above shortcoming. Specifically, the Muntwyler et al. reference is directed to a specific group of halogenated 3-hydroxydiphenyl ethers that have a particularly effective action against gram-positive and gram-negative bacteria and fungi. In one embodiment, the ethers can be used in cosmetic preparations, e.g., volatile oils, bath salts, brilliantines, ointments, face lotions, hair dyeing preparations, hair oils, hair tonics, skin creams, skin oils, Eau-de-Cologne, perfumes, powders, rouge, depilatories, sun-ray filter creams and dental hygiene products.¹⁰ Additionally, the ethers can be used in combination with known antibacterial agents. One such antibacterial agent for combination with the ethers is phenoxyethanol.¹¹

Significantly, nowhere in Muntwyler et al. is it disclosed to use their antibacterial ether compounds for the treatment of vaginal fungal, bacterial, viral, and parasitic infections. As such, one skilled in the art would not, and could not, be motivated to use the antibacterial ether compounds of Muntwyler et al. over any other antibacterial compounds in the intravaginal devices of D' Augustine et al. to arrive at each and every limitation of Applicants' claims 11-13. As such,

¹⁰ Muntwyler et al. at column 10, lines 7-13.

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claims 11-13 are patentable over Stolar and D'Augustine et al.
or Chen and D'Augustine et al. in view of Stolar and further in
view of Muntwyler et al.

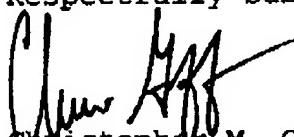
¹¹ Muntwyler et al. at column 10, lines 20-30.

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Conclusion

In view of the above, Applicants respectfully request favorable reconsideration and allowance of all pending claims. The Commissioner is hereby authorized to charge any fee deficiency in connection with this Letter To Patent And Trademark Office to Deposit Account Number 19-1345 in the name of Senniger, Powers, Leavitt & Roedel.

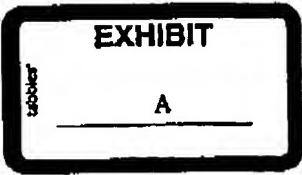
Respectfully Submitted,



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UNITED STATES PATENT AND TRADEMARK OFFICE

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UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

MARCH 15, 2005

PTAS



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UNITED STATES PATENT AND TRADEMARK OFFICE
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PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 09/10/2004

REEL/FRAME: 015772/0798
NUMBER OF PAGES: 4

BRIEF: ASSIGNMENT OF ASSIGNEE'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNEE:	
✓ KIMBERLY-CLARK WORLDWIDE, INC. 401 N. LAKE STREET NEENAH, WISCONSIN 54957	DOC DATE: 05/10/2004
✓ SERIAL NUMBER: 10803819 PATENT NUMBER:	FILING DATE: 03/18/2004
✓ TITLE: INHIBITION OF EXOPROTEIN PRODUCTION USING AROMATIC COMPOSITIONS IN NON-ABSORBENT ARTICLES	ISSUE DATE:

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DELPHINE TIMBERLAKE, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

09-13-2004

Form PTO-1595
 (Rev. 10/02)
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U. S. DEPARTMENT OF COMMERCE
 U.S. Patent and Trademark Office

<p>To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.</p> <p>1. Name of conveying party(ies): <u>Rae Ellen Syverson</u> <u>Richard A. Proctor</u></p> <p>Additional name(s) of conveying party(ies) attached? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>3. Nature of conveyance: <input checked="" type="checkbox"/> Assignment <input type="checkbox"/> Merger <input type="checkbox"/> Security Agreement <input type="checkbox"/> Change of Name <input type="checkbox"/> Other _____</p> <p>Execution Date: <u>5/10/04</u></p>		<p>2. Name and address of receiving party(ies) Name: <u>Kimberly-Clark Worldwide, Inc.</u></p> <p>Internal Address: _____</p> <p>Street Address: <u>401 N. Lake Street</u></p> <p>City: <u>Neenah</u> State: <u>WI</u> Zip: <u>54957</u></p> <p>Additional name(s) & address(es) attached? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>4. Application number(s) or patent number(s): If this document is being filed together with a new application, the execution date of the application is: _____</p> <p>A. Patent Application No.(s) <u>10/803,819</u></p> <p>B. Patent No.(s) _____</p> <p>Additional number(s) attached <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>5. Name and address of party to whom correspondence concerning document should be mailed: Name: <u>Christopher M. Goff</u></p> <p>Internal Address: <u>SENNIGER POWERS</u></p> <p>Street Address: <u>One Metropolitan Square, 16th Floor</u></p> <p>City: <u>St. Louis</u> State: <u>Missouri</u> Zip: <u>63102</u></p> <p>6. Total number of applications and patents involved: <u>1</u></p> <p>7. Total fee (37 CFR 3.41) \$ <u>40.00</u> <input checked="" type="checkbox"/> Enclosed <input type="checkbox"/> Authorized to be charged to deposit account</p> <p>8. Deposit account number: <u>19-1345</u></p> <p>(Attach duplicate copy of this page if paying by deposit account)</p> <p>DO NOT USE THIS SPACE</p> <p>9. Signature. <u>Christopher M. Goff</u> Name of Person Signing</p> <p>Signature <u>Chris M. Goff</u> Date <u>09/02/04</u></p> <p>Total number of pages including cover sheet, attachments, and document: <u>4</u></p> <p>Mail documents to be recorded with required cover sheet information to: Mail Stop Assignment Recordation Services Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450</p>
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ASSIGNMENT

WHEREAS, We Rae Ellen Syverson of Fond du Lac, Wisconsin and Richard A. Proctor of Madison, Wisconsin, have invented an improvement in INHIBITION OF EXOPROTEIN PRODUCTION USING AROMATIC COMPOSITIONS IN NON-ABSORBENT ARTICLES (File KCC 4749.1; K-C 16,858.1) and have executed an application for a United States patent based thereon Serial No. 10/803,819, filed March 18, 2004;

AND, WHEREAS, Kimberly-Clark Worldwide, Inc. of Neenah, Wisconsin, a corporation of the State of Delaware (hereinafter referred to as "ASSIGNEE") is desirous of acquiring certain rights thereunder;

NOW, THEREFORE, for one dollar and other good and valuable consideration, receipt of all of which is hereby acknowledged, we have agreed to and do hereby sell, assign and transfer unto said ASSIGNEE the entire right, title and interest in and throughout the United States of America (including its territories and dependencies) and all countries foreign thereto in and to said invention, said United States application, any other United States applications (including provisional, non-provisional, divisional, continuing, or reissue applications) based in whole or in part on said United States application or in whole or in part on said invention, any foreign applications based in whole or in part on any of the aforesaid United States applications or in whole or in part on said invention, and any and all patents (including extensions thereof) of any country which have been or

may be granted on any of the aforesaid applications or on said invention or any part thereof;

TO BE HELD AND ENJOYED by said ASSIGNEE, its successors and assigns, as fully and entirely as the same would have been held and enjoyed by us had no sale and assignment of said interest been made;

AND We hereby authorize and request the Commissioner of Patents of the United States of America to issue any and all United States patents which may be granted upon said United States applications or any of them, or upon said invention or any part thereof, to said ASSIGNEE;

AND We hereby jointly and severally agree for ourselves and for our respective heirs, executors and administrators, to execute without further consideration any further lawful documents and any further assurances, and any provisional, non-provisional, divisional, continuing, reissue, or other applications for patents of any country, that may be deemed necessary by said ASSIGNEE fully to secure to said ASSIGNEE its interest as aforesaid in and to said invention or any part thereof, and in and to said several patents or any of them;

AND We hereby jointly and severally covenant for ourselves and our respective legal representatives that we have granted no right or license to make, use or sell said invention, to anyone except said ASSIGNEE, that prior to the execution of this deed our right, title and interest in said invention had not been

otherwise encumbered, and that we have not executed and will not execute any instrument in conflict herewith.

IN WITNESS WHEREOF, we have hereunto set our hands.

5/10/04
Date

Rae Ellen Syverson
Rae Ellen Syverson

10 May 04
Date

Richard A. Proctor
Richard A. Proctor

CMG/dmt

Section I—Common Health Problems - Vaginal Problems

HealthyLife® Students' Self-Care Guide

EXHIBIT**B**

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Table of Contents**Section I—Common Health Problems**[Previous Topic](#) | [Next Topic](#)

Vaginal Problems

"I just learned that yogurt could help to prevent yeast infections. Now when I take antibiotics, I eat a yogurt in the morning to help keep clear from any problems."

Kim P., University of Maryland

Vaginal problems include vaginal pain, discharge, abnormal bleeding, irritation, and/or infections. Infections may or may not be sexually transmitted. Common vaginal problems in college age females are listed below.

Signs, Symptoms & Causes

Bacterial Vaginosis

This is an infection from one or more types of bacteria. With this you may have:

- Mild vaginal irritation or burning
- A watery, grayish-white, or yellow vaginal discharge with a fishy odor

Pelvic Inflammatory Disease (PID)

This is an infection of the uterus, fallopian tubes, and/or ovaries. With PID, you have vaginal bleeding with 2 or more of these problems:

- Abdominal tenderness and/or bloating
- Pain in the pelvis, lower abdomen, or back. The pain can be severe enough to make you walk bent over and to take small steps.
- Pain during intercourse
- The skin on your abdomen feels sensitive.
- Vaginal discharge with abnormal color or odor
- Change in menstrual flow
- Fever, chills

Vaginal Yeast Infection

This is caused by an overgrowth of the fungus, *Candida albicans*, which is normally present in the vagina. Taking some brands of birth control pills and/or an antibiotic may trigger this overgrowth.

Symptoms of a vaginal yeast infection are:

- Itching, irritation, and redness around the vagina
- Thick, white vaginal discharge that looks like cottage cheese and may smell like yeast
- Burning and/or pain with urinating or during sex

Vaginitis From Contact Dermatitis

Section I-Common Health Problems - Vaginal Problems

Page 2 of 5

This is a reaction to products that irritate the vaginal area, such as harsh detergents, scented items, douches, latex condoms, and tight-fitting clothing. With this, you have itching and redness in the outer genital area without other symptoms.

Sexually Transmitted Diseases

These include genital herpes, genital warts, gonorrhea, and trichomoniasis. (See **signs and symptoms of sexually transmitted diseases.**)

Treatment

Treatment for the vaginal problem depends on the cause. Bacterial infections and PID are treated with antibiotics. Fungal infections are treated with antifungal medicines.

Questions to Ask

Has a recent sexual assault or major injury to the abdomen, pelvis, or vagina occurred?

 Yes. Get Immediate Care.

NO

Do you have vaginal pain that spreads upward to the pelvis and you are unable to walk due to the pain?

 Yes. Get Immediate Care.

NO

Does vaginal irritation and/or pain occur with all of the symptoms of a kidney infection?

 Yes. Get Immediate Care.

NO

Do you have very heavy vaginal bleeding (you saturate more than 1 full size pad or super absorbent tampon in an hour's time) with any of the following problems?

- Dizziness, feeling faint, or feeling lightheaded when you sit up
- Pale and moist skin
- Extreme shortness of breath or a very hard time breathing
- Severe abdominal pain

 Yes. Get Immediate Care.

NO

Do you have any of the following?

Section I-Common Health Problems - Vaginal Problems

Page 3 of 5

- **Signs and symptoms of Pelvic Inflammatory Disease (PID)**
- **Signs and symptoms of bacterial vaginosis**
- **Signs and symptoms of a sexually transmitted disease**

NO

Do any of the following apply?

- You have had 3 or more vaginal infections within 3 months time.
- After diagnosis and 72 hours of treatment for a vaginal infection, your symptoms continue.
- Vaginal pain occurs during or after sexual intercourse.

NO

Do you have bleeding in the vaginal area from itching due to vaginal irritation?

NO

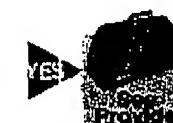
Do you have vaginal bleeding with any of these problems?

- Increased vaginal bleeding or you continue to have spotting or bleeding between your periods after 3 months of taking birth control pills. (Your dose may need to be adjusted.)
- Bleeding heavier than your normal period (you are saturating almost or equal to 1 full pad or tampon every hour)
- Nausea, vomiting, or abdominal pain
- Increasing pain and tenderness in your vaginal area
- Menstrual periods that are abnormally heavy or long (>10 days)
- Heavy menstrual periods and passing many small or large blood clots and you are pale and feel very tired

NO

With vaginal pain, do you use an IUD for birth control and do any of the following conditions apply?

- The IUD was inserted during the last 4 to 6 weeks.
- The strings from the IUD cannot be felt.
- The IUD can be felt through the vagina. (An IUD can become embedded in the wall of the uterus. When this happens, surgery is needed to remove the IUD.)



Section I—Common Health Problems - Vaginal Problems

Page 4 of 5



Has a vaginal discharge or irritation been present for longer than 1 week despite using Self-Care?



Self-Care/Prevention

For Vaginitis from Contact Dermatitis:

- Avoid products that cause the problem (scented items, douches, feminine hygiene sprays, etc.). Don't scrub the affected area with a washcloth.
- Don't wear tight and constricting garments (girdles, tight blue jeans, etc.).
- Use medicated wipes, such as Tucks, instead of dry toilet paper. Follow package directions.
- Add an oatmeal bath product (Aveeno) or baking soda to bath water.
- Apply an over-the-counter 1% hydrocortisone cream to the affected area. Use this infrequently, though. Hydrocortisone can lead to a thinning of the vaginal tissue.
- Put a cool compress on the affected area.
- Take a sitz bath every 4 to 6 hours or as needed. A sitz bath basin is a device that fits on the toilet seat and is used to cleanse the genital area. You can buy a sitz bath basin at a medical supply store and at some drug stores.
- Wash your underwear in a gentle detergent. Rinse it twice. Use only plain water for the second rinse. Don't use fabric softener.

For a Vaginal Yeast Infection:

- If you have a history of vaginal yeast infections and these current symptoms are the same and you used an over-the-counter remedy successfully in the past, use the same or similar product. Use vaginal creams or suppositories, such as Monistat and Gyne-Lotrimin. If you get a vaginal yeast infection when you take an antibiotic, use one of these over-the-counter products during and/or after the period of antibiotic treatment.
- Limit your intake of sugar and foods that contain sugar. Sugar promotes the growth of yeast.
- Eat yogurt and/or take an over-the-counter product that contains live cultures of lactobacillus acidophilus.
- Take showers, not baths. Avoid bubble baths.
- Keep the vagina as clean and dry as possible.
- Wear cotton or cotton-lined underwear.
- Don't wear tight and constricting garments (girdles, tight blue jeans, etc.).
- Wear knee-highs instead of panty hose, if possible. When you wear panty hose, wear ones with cotton crotches.



For Information, Contact:

National Women's Health Information Center
800.994.WOMAN
www.4women.gov

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July 21, 2003

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Vaginal Problems

"I just learned that yogurt could help to prevent yeast infections. Now when I take antibiotics, I eat a yogurt in the morning to help keep clear from any problems."

Kim P., University of Maryland

Vaginal problems include vaginal pain, discharge, abnormal bleeding, irritation, and/or infections. Infections may or may not be sexually transmitted. Common vaginal problems in college age females are listed below.

Signs, Symptoms & Causes

Bacterial Vaginosis

This is an infection from one or more types of bacteria. With this you may have:

- Mild vaginal irritation or burning
- A watery, grayish-white, or yellow vaginal discharge with a fishy odor

Pelvic Inflammatory Disease (PID)

This is an infection of the uterus, fallopian tubes, and/or ovaries. With PID, you have vaginal bleeding with 2 or more of these problems:

- Abdominal tenderness and/or bloating
- Pain in the pelvis, lower abdomen, or back. The pain can be severe enough to make you walk bent over and to take small steps.
- Pain during intercourse
- The skin on your abdomen feels sensitive.
- Vaginal discharge with abnormal color or odor
- Change in menstrual flow
- Fever, chills

Vaginal Yeast Infection

This is caused by an overgrowth of the fungus, *Candida albicans*, which is normally present in the vagina. Taking some brands of birth control pills and/or an antibiotic may trigger this overgrowth.

Symptoms of a vaginal yeast infection are:

- Itching, irritation, and redness around the vagina
- Thick, white vaginal discharge that looks like cottage cheese and may smell like yeast
- Burning and/or pain with urinating or during sex

Vaginitis From Contact Dermatitis

Section I—Common Health Problems - Vaginal Problems

Page 2 of 5

This is a reaction to products that irritate the vaginal area, such as harsh detergents, scented items, douches, latex condoms, and tight-fitting clothing. With this, you have itching and redness in the outer genital area without other symptoms.

Sexually Transmitted Diseases

These include genital herpes, genital warts, gonorrhea, and trichomoniasis. (See signs and symptoms of sexually transmitted diseases.)

Treatment

Treatment for the vaginal problem depends on the cause. Bacterial infections and PID are treated with antibiotics. Fungal infections are treated with antifungal medicines.

Questions to Ask

Has a recent sexual assault or major injury to the abdomen, pelvis, or vagina occurred?



NO

Do you have vaginal pain that spreads upward to the pelvis and you are unable to walk due to the pain?



NO

Does vaginal irritation and/or pain occur with all of the symptoms of a kidney infection?



NO

Do you have very heavy vaginal bleeding (you saturate more than 1 full size pad or super absorbent tampon in an hour's time) with any of the following problems?

- Dizziness, feeling faint, or feeling lightheaded when you sit up
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- Extreme shortness of breath or a very hard time breathing
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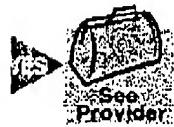
NO

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Section I-Common Health Problems - Vaginal Problems

Page 3 of 5

- Signs and symptoms of Pelvic Inflammatory Disease (PID)
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NO

Do any of the following apply?

- You have had 3 or more vaginal infections within 3 months time.
- After diagnosis and 72 hours of treatment for a vaginal infection, your symptoms continue.
- Vaginal pain occurs during or after sexual intercourse.



NO

Do you have bleeding in the vaginal area from itching due to vaginal irritation?



NO

Do you have vaginal bleeding with any of these problems?

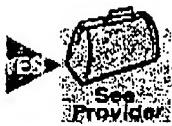
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Section I-Common Health Problems - Vaginal Problems

Page 4 of 5

NO

Has a vaginal discharge or irritation been present for longer than 1 week despite using Self-Care?



NO



Self-Care/Prevention

For Vaginitis from Contact Dermatitis:

- Avoid products that cause the problem (scented items, douches, feminine hygiene sprays, etc.). Don't scrub the affected area with a washcloth.
- Don't wear tight and constricting garments (girdles, tight blue jeans, etc.).
- Use medicated wipes, such as Tucks, instead of dry toilet paper. Follow package directions.
- Add an oatmeal bath product (Aveeno) or baking soda to bath water.
- Apply an over-the-counter 1% hydrocortisone cream to the affected area. Use this infrequently, though. Hydrocortisone can lead to a thinning of the vaginal tissue.
- Put a cool compress on the affected area.
- Take a sitz bath every 4 to 6 hours or as needed. A sitz bath basin is a device that fits on the toilet seat and is used to cleanse the genital area. You can buy a sitz bath basin at a medical supply store and at some drug stores.
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- Limit your intake of sugar and foods that contain sugar. Sugar promotes the growth of yeast.
- Eat yogurt and/or take an over-the-counter product that contains live cultures of lactobacillus acidophilus.
- Take showers, not baths. Avoid bubble baths.
- Keep the vagina as clean and dry as possible.
- Wear cotton or cotton-lined underwear.
- Don't wear tight and constricting garments (girdles, tight blue jeans, etc.).
- Wear knee-highs instead of panty hose, if possible. When you wear panty hose, wear ones with cotton crotches.



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July 21, 2003

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**EXHIBIT**

C

HYDROCORTISONE - LABELLING STANDARD**CATEGORY:** Anti-pruritic/Anti-inflammatory**DEFINITION:** Hydrocortisone cream, gel, lotion, ointment
Hydrocortisone acetate cream, lotion, ointment**MEDICINAL INGREDIENTS
AND CONCENTRATIONS:**

All finished product and ingredients used in the manufacture of the product should comply with the specifications of Schedule B pharmacopoeial or equivalent standard.

The medicinal ingredients of a product complying with this standard consist of the following ingredients when used singly or in acceptable combinations within the established limits given:

- Hydrocortisone (0.5%)
- Hydrocortisone (Acetate) (0.5%)

PERMITTED COMBINATIONS:**ADEQUATE DIRECTIONS FOR USE:****Indications:**

- For temporary relief of minor skin irritations associated with redness, itching, dryness and scaling
- For temporary relief of minor skin irritations, itching and redness due to eczema, dermatitis, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics and jewellery

* itchy genital and anal areas has been accepted.

Dosage Directions:

- apply to affected area not more than 3 or 4 times daily
- use for only 7 days maximum
- if symptoms persist beyond 7 days or return after discontinuing use of product, consult your physician
OR
- if condition worsens or if symptoms persist for more than 7 days, discontinue use and consult a physician

Canada

2

created:86-11-14
revised:91-04-11

Warnings:

- do not use in or around the eyes
- do not apply to large areas
- not to be used to treat vulvar itching associated with a vaginal discharge (except on the advise of a physician)
- external use only
- do not use on children 2 years of age or younger, unless directed by a physician

NOTE: This labelling standard describes those requirements that are specific to this class of drugs. Other requirements described in the Regulations to the Food and Drugs Act and in the Guide for the Labelling of Drugs for Human Use should also be met.

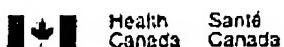
REFERENCES:

1. Information Letter 678, Recommendations of the Expert Advisory Committee on Dermatology Regarding the Availability of Over-the-Counter Topical Preparations Containing Hydrocortisone, March 22, 1985.
2. United States Pharmacopeia XXII, 1990.
3. British Pharmacopeia, 1988.

Product Regulation Division
Bureau of Nonprescription Drugs
created:86-11-14
revised:91-04-11

Hydrocortisone

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HYDROCORTISONE - LABELLING STANDARD

Hydrocortisone

CATEGORY: Anti-pruritic/Anti-inflammatory

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Hydrocortisone

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